

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

WEST, et al.

Serial No.: 10/551,203

PCT Filed: March 3, 2005

Art Unit: (not yet assigned)

Examiner: (not yet assigned)

Atty. Docket No.: 05-167-US



ALKALOID FORMULATIONS

Commissioner for Patents

MAIL STOP PETITION

P.O. Box 1450

Alexandria, VA 22313-1450

PETITION TO MAKE SPECIAL
UNDER 37 C.F.R. § 1.102 (M.P.E.P. § 708.02)

Sir:

Applicants hereby petition the Commissioner to make the above-identified application special in accordance with 37 C.F.R. § 1.102(d). Pursuant to M.P.E.P. § 708.02(VIII), Applicants state the following.

07/06/2006 TBESHAH1 00000001 10551203

01 FC:1464

130.00 OP

(A) This Petition is accompanied by the fee set forth in 37 C.F.R. § 1.17(h).

A check in the amount of \$130.00 representing the Group III petition fee is enclosed herewith.

(B) All claims are directed to a single invention.

If the Office determines that all claims are not directed to a single invention, Applicant will make an election without traverse as a prerequisite to the grant of special status in conformity with established telephone restriction practice.

130.00 OP

(C) A pre-examination search has been conducted.

The search was directed towards an alkaloid formulation. The search was further directed to a method for improving the efficacy of an alkaloid, the use of the reaction product of one or more alkaloids with one or more phosphate derivatives of one or more electron transfer agents, together with excipients in the manufacture of a formulation and a pharmaceutical composition comprising the reaction product of one or more alkaloids with one or more phosphate derivatives of one or more electron agents.

In particular, the search was directed towards independent Claim 1, which recites an alkaloid formulation comprising the reaction product of one or more alkaloids with one or more phosphate derivatives of one or more electron transfer agents.

In particular, the search was also directed towards independent Claim 19, which recites a method for improving the efficacy of an alkaloid, said method comprising the step of reacting the alkaloid with one or more phosphate derivative of one or more electron transfer agents.

In particular, the search was also directed towards independent Claim 20, which recites the use of the reaction product of one or more alkaloids with one or more phosphate derivatives of one or more electron transfer agents, together with excipients in the manufacture of a formulation.

In particular, the search was also directed towards independent Claim 21, which recites a pharmaceutical composition comprising the reaction product of one or more alkaloids with one or more phosphate derivatives of one or more electron transfer agents.

The search of the above features was conducted in the following areas:

<u>International Classes</u>	<u>Subclasses</u>
A61K	31/46
A61K	31/485
A61K	31/355
A61P	29/00

A search of the above features was also conducted in the DWPI and CA electronic databases.

These searches were conducted by the Australian Patent Office, in its capacity as the International Search Authority for the underlying International Patent Application, Serial No. PCT/AU2005/000307, on April 26, 2005. A copy of the International Search Report summarizing the search results is attached as Exhibit A.

(D) The following is a list of the references deemed most closely related to the subject matter encompassed by the claims.

U.S. PATENT DOCUMENTS

Patent Number	Issue Date	Patentee
6384043	5/2002	Peyman et al.

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

Document Number	Publication Date	Country or Patent Office
WO 2004/014432	2/2004	WO
WO 2003/024429	3/2003	WO
WO 2003/024430	3/2003	WO
JP 025-201858	8/1993	JP (abstract)

A copy of each of these references (as well as other references revealed during the search) has either already been submitted earlier in prosecution of this application or is being submitted herewith in connection with the accompanying Information Disclosure Statement.

(E) It is submitted that the present invention is patentable over the references for the following reasons.

It is submitted that the cited references, whether taken individually or in combination with each other, fail to teach or suggest the invention as claimed. In particular, the cited references, at a minimum, fail to teach or suggest in combination with the other limitations recited in the claims the primary feature of the present invention as recited in independent Claims 1, 19, 20 or 21, of formulations comprising one or more alkaloids, more specifically but not exclusively, to formulations comprising one or more alkaloids and one or more phosphate derivatives of electron transfer agents as used in the present invention.

To the extent applicable to the present Petition, Applicants submit that although the distinguishing features may represent a substantial portion of the claimed invention, the claimed invention including said features and their inter-operation provides a novel method, composition and use thereof of alkaloid formulations.

The references considered most closely related to the claimed invention are briefly discussed below:

WO 2004/014432 (“WO 432”)

WO 432 discloses a carrier for pharmaceuticals, the carrier comprising a complex of a phosphate derivative of and electron transfer agent or a phosphate derivative of an electron transfer agent. There is no disclosure in WO 432 of an

alkaloid formulation comprising the reaction product of an alkaloid with a phosphate derivative of an electron transfer agent.

WO 2003/024429 (“WO 429”)

WO 429 discloses a matrix composition for controlled release of a pharmaceutical. There is no disclosure in WO 429 of an alkaloid formulation comprising the reaction product of an alkaloid with a phosphate derivative of an electron transfer agent.

WO 2003/024430 (“WO 430”)

WO 430 discloses a matrix composition for controlled release of a pharmaceutical. There is no disclosure in WO 430 of an alkaloid formulation comprising the reaction product of an alkaloid with a phosphate derivative of an electron transfer agent.

US 6384043 (“US 043”)

US 043 discloses solutions of morphine and Vitamin E for ophthalmic uses. Vitamin E comprises tocopherol and not tocopheryl phosphate. There is no disclosure in US 043 of an alkaloid formulation comprising the reaction product of an alkaloid with a phosphate derivative of an electron transfer agent.

JP 05-201858 (“JP 858”)

JP 858 discloses a formulation comprising ascorbic acid and an ephedrine-type alkaloid. There is no disclosure in JP 858 of an alkaloid formulation comprising the reaction product of an alkaloid with a phosphate derivative of an electron transfer agent.

Therefore, since the cited references fail to teach or suggest the above described features of the present invention as recited in each of the independent claims in combination with the other limitations recited in each of the independent claims, it is

submitted that all of the claims are patentable over the cited references whether said references are taken individually or in combination with each other.

(F) Conclusion

What the Applicant considers to be a reasonable search has been conducted, though Applicant makes no representation that "better" or more relevant prior art does not exist. The United States Patent and Trademark Office is urged to conduct its own complete search of the prior art, and to thoroughly examine this application in view of the prior art cited herein and any other prior art that the United States patent and Trademark Office may locate in its own independent search. Further, while Applicant has identified in good faith certain portions of each of the references listed herein in order to provide the requisite detailed discussion of how the claimed subject matter is patentable over the references, the United States Patent and Trademark Office should not limit its review to the identified portions but rather, is urged to review and consider the entirety of each reference, and not to rely solely on the identified portions when examining this application.

In view of the foregoing, Applicant requests that this Petition to Make Special be granted and that the application undergo the accelerated examination procedure set forth in M.P.E.P. § 708.02 (VIII).

Respectfully submitted,



James G. Dilmore
Reg. No. 51,618

Dated: June 29, 2006

REED SMITH LLP
P.O. Box 488
Pittsburgh, PA 15230-0488
(412) 288-3813

Agent for Applicants